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Mallinckrodt Plc Call to Discuss SpinOff of Specialty Generics Business - Final

Presentation

OPERATOR: Good day, ladies and gentlemen, and welcome to the Mallinckrodt conference call. (Operator Instructions) As a reminder, this call is being recorded.

I would now like to introduce your host for today's conference, Mr. Dan Speciale, Investor Relations and Strategy Officer. Please go ahead.

DANIEL J. SPECIALE, IR & STRATEGY OFFICER, MALLINCKRODT PUBLIC LIMITED COMPANY: Thank you, Christie. Good morning, everyone, and thank you for joining us on short notice. Joining me today are Mark Trudeau, our CEO; and Matt Harbaugh, the president of our Specialty Generics business. We'll start by making a few prepared remarks on the announced plan to spin off our specialty generics business, and we'll then move to a half an hour or so of Q&A to address your questions. As we move to Q&A, we'd ask you to please try to focus your questions to the announcement this morning. Before we begin, let me remind you of a few important details. On the call, you'll hear us make some forward-looking statements, and it's possible actual results could be materially different from our stated expectations. Please note, we assume no obligation to update any forward-looking statements even if actual results or future expectations change materially. We encourage you to refer to the cautionary statements contained in our SEC filings for a more in-depth explanation of the inherent limitations of such forward-looking statements. As noted in our 8-K this morning, we've prepared a slide deck on the planned separation, which can be found on our website, mallinckrodt.com. We use our website as a channel to distribute important time-critical company information. And you should look to the Investor Relations page of our website for this information.

With that, let me turn the call over to Mark. Mark?

MARK CHRISTOPHER TRUDEAU, PRESIDENT, CEO & DIRECTOR, MALLINCKRODT PUBLIC LIMITED COMPANY: Thanks, Dan. This morning's announcement of our plan to spin off our Specialty Generics business marks a particularly significant milestone in Mallinckrodt's transformation to become an innovation-driven, pure-play specialty pharmaceutical brands growth company focused on improving outcomes for underserved patients with severe and critical conditions.

Those who have followed our journey will know that, over the past 5 years, we've undertaken a deliberate, carefully orchestrated series of transactions to build a portfolio of marketed and developmental pharmaceutical brands to drive growth while, at the same time, separating those assets that were not core to our future and could be better maximized in the hands of others.

With this transaction, we will exit the last of our legacy businesses. Our intent is to transition the specialty generics business, and it's been clear for some time. In September 2016, our Board of Directors met and reviewed an array of strategic options for this business, including a sale, either as a whole or in parts, a range of partnership opportunities and various spin-off alternatives.

Following that discussion, we began separating the Specialty Generics operations from the specialty pharmaceutical brands business, so we could quickly execute when the time came.

And we've been consistent in our public statements that we were managing the business primarily for cash. As this morning's announcement indicates, we think the strategic business rationale for a spin-off is strong and that it's a highly attractive way to complete the final separation of our legacy businesses. The transaction has the opportunity to create 2 independent appropriately capitalized publicly traded companies, one focused on innovative specialty pharmaceutical brands and the other on niche specialty generic products and API manufacturing with each positioned to unlock an increased value over the long term and optimize future success as they pursue independent growth strategies.

Today, Specialty Generics and Specialty Pharmaceutical brands have distinct business models and each is impacted by a divergent set of market dynamics. The planned separation will allow the respective management teams to focus on and commit to the long-term strategic priorities aligned with each company's stakeholders. Operating independently should let the Specialty Generics company more rapidly capitalize on its growth opportunities to enhance value. And though the vision and strategic direction of the Specialty Pharmaceutical brands business will be unchanged by the transaction, the business should benefit from the expected additional liquidity associated with the spin.

We expect the separation to be affected through a pro rata distribution of common stock to Mallinckrodt shareholders, a transaction that we anticipate will be generally tax free for U.S. federal income tax purposes.

Further, because so much work has been done over the past few years to position Specialty Generics as a standalone business within our portfolio, we expect to be able to move rather quickly and anticipate completion of the spin-off in the second half of 2019 or sooner, assuming all of the customary prerequisites are met.

Though the ultimate decision to spin and the allocation of assets to include in the spin is subject to final board approval, let me describe the scope of what we believe will likely be included in the transaction as the profile of the new spin co will be larger than the Specialty Generics disposal group now in discontinued operations.

The independent publicly traded company we plan to distribute to our shareholders will consist of Mallinckrodt's Specialty Generics and active pharmaceutical ingredients businesses, including various legacy assets and supply agreements. It will also include certain non-promoted branded products, including the AMITIZA product in North America and Japan and its related Japanese manufacturing facilities and employees. The risks and liabilities associated with these businesses, including certain legacy environmental matters will follow the assets in the spin.

Another asset included in the spin is the Mallinckrodt name. Founded in St. Louis over 150 years ago, Mallinckrodt has long been associated with supply chain excellence and recognized for the expertise in formulation and complex chemistry that's necessary to succeed in the generics industry.

The name will provide significant value to the Specialty Generics business, and we will rename the Specialty Pharmaceutical brands company at a later date.

We're also planning to establish the company with a known and proven leader in Matt Harbaugh, who will expect to become its President and Chief Executive Officer upon completion of the spin-off. This is an exciting opportunity for Matt, and you'll hear from him in a minute.

As I mentioned, at spin, we expect each business will be appropriately capitalized with cash on the balance sheet and a debt structure aligned with the mix of assets in its respective portfolio. The Specialty Brands company plans to use any proceeds from the spin to support further investments in its in-line brands and development portfolio in addition to pursuing strategic capital allocation consistent with its previously stated priorities.

We will provide updates on the capital structure for each company as we get closer to spin.

Now let me turn the call over to Matt, so he can provide additional color on the Specialty Generics and AMITIZA business. Matt?

MATTHEW K. HARBAUGH, EXECUTIVE VP & PRESIDENT OF THE SPECIALTY GENERICS BUSINESS, MALLINCKRODT PUBLIC LIMITED COMPANY: Thanks, Mark. This is an exciting day, not only for me, but for all of Mallinckrodt's approximately 1,600 Specialty Generics and AMITIZA employees. In the last few years, the Specialty Generics business has assumed a supporting player role within Mallinckrodt. This isn't surprising given the fact that when making the kind of significant strategic portfolio transition that Mallinckrodt has been undertaking, capital is naturally focused on opportunities associated with that vision. Separation by means of a spin-off will present new opportunities for Specialty Generics to direct its cash flows to reinvestments in its own distinct strategic vision.

Specialty Generics has been in discontinued operations for some time, and we haven't really talked about it other than to confirm that we were still exploring a range of strategic alternatives for divesting the business.

So it would probably serve us well to remind everyone about some of the many elements of this business.

Specialty Generics is a niche, U.S.-based company known for its formulation capabilities and expertise in specialized chemistry, and it has an industry-leading reputation for quality, integrity and service.

The business is vertically integrated with R&D, manufacturing and commercial capabilities, and its customers appreciate the consistency and continuity of supply it offers.

Specialty Generics is a leading manufacturer of controlled substances, both in API and finished dosage, with increasing market share particularly in finished products.

But the business is broader than that. As Mark mentioned, AMITIZA has been included in the planned spin-off for several strategic reasons. The first is that AMITIZA is managed through established commercial partnerships and, as such, it resembles a number of other non-promoted brands for pain, addiction treatment and ADHD that are already in the Specialty Generics portfolio today.

AMITIZA's royalty stream along with its Japanese manufacturing facilities and people should also enhance the financial profile of the business and be enabling assets, providing scale and revenue diversification, positioning Specialty Generics to be successful as it pursues its own strategic vision.

From a forward-looking net sales perspective, we anticipate roughly 40% of the business will come from APIs; approximately 35% will come from specialty generic dosage products; and the remaining 25% will come from AMITIZA and other non-promoted brands.

Specialty Generics also has an ANDA pipeline of complex generics that we believe positions the business for growth longer term. And the company expects to launch as many as 5 new products in 2019 alone. The business plans to

make focused R&D investments that leverage its core formulation capabilities and also has a thoughtful and purposeful pipeline selection process that focuses on high-value projects with a high technical probability of success.

As you would expect, we've already begun work to identify the appropriate governance structure for the new business and are actively engaged in selecting a Board of Directors. More information on these activities in the Specialty Generics company and pipeline will be set forth in the Form 10 that should become publicly available during the first half of 2019.

Before handing the call back over to Mark, let me briefly comment on a technical accounting matter mentioned in our release, how the spin-off plans impact discontinued operations treatment. As a result of today's announcement, in accordance with the accounting literature related to discontinued operations, we expect the Specialty Generics disposal group to return to Mallinckrodt's continuing operations with our next quarterly earnings announcement in our 2018 Form 10-K.

We're presently exploring ways to align the segments of continuing operations with today's announced profiles of both the Specialty Generics and Specialty Pharmaceuticals brands business.

Back to you, Mark.

MARK CHRISTOPHER TRUDEAU: Thanks, Matt. We're very pleased to have someone with Matt's leadership experience and knowledge of the industry poised to take over at the helm of the new Specialty Generics company if the transaction is completed.

Matt was serving as interim president of the Pharmaceuticals business when I joined Mallinckrodt, and he's been a trusted adviser to me and the board as our CFO.

While he steps down from his CFO role today to focus on the spin, Matt will continue to serve as the president of Specialty Generics and report to me.

As you might also expect, our search for Matt's successor is well underway. We've asked George Kegler to serve as our interim CFO until the search concludes. George brings more than 40 years of experience to the position, including a past CFO role, and he has worked directly for Matt for nearly 6 years.

As is always the case with this sort of announcement, there are many more details to come. And we plan to share key developments with you as appropriate when we progress towards separation. While we will continue to evaluate all strategic options, including a sale, to maximize the value of the Specialty Generics and AMITIZA assets, we believe our plan to create 2 publicly traded companies with scale and focus is in the best interest of our shareholders.

The spin should improve each company's ability to achieve its respective strategic goals and unlock value.

Now let me turn the call back to Dan.

DANIEL J. SPECIALE: Thanks, Mark. Matt mentioned the move of the disposable back into continuing operations. This will currently impact our previously announced 2018 annual guidance in a positive way. There's still much work to be done to recast the historical financial information. However, you should expect to see an increase to our reported adjusted diluted earnings per share for 2018 from the previous guidance range of $7 to $7.20 as we move these results back into continuing operations. We plan to provide full recast financials by quarter in conjunction with our Q4 earnings release and the filing of our Form 10-K. And we expect to address guidance for 2019 as this work is completed.

We'll now move into Q&A and work through any questions you have related to the announcement today in the planned spin-off. I assure you we'll get through each of your questions, but please limit yourself to a single question going back in queue afterwards if you have any follow-ups.

With that operator, may we please have the first question.

Questions and Answers

OPERATOR: (Operator Instructions) Our first question is from Gary Nachman from BMO Capital Markets.

GARY JAY NACHMAN, ANALYST, BMO CAPITAL MARKETS EQUITY RESEARCH: I know it's early here but what are the operating margins expected for each of the businesses, brand and generics? And then describe the additional liquidity you talked about for the brand business from the spin, maybe order of magnitude that you anticipate at this point?

MARK CHRISTOPHER TRUDEAU: So maybe I'll take the second question first, Gary, and then I'll ask Dan to comment on the margin question. So our plan is to make this a levered spin. And as I mentioned in the prepared remarks, what we plan to do for each company is create an appropriate capital structure that reflects the asset mix that each company ends up with after the spin, which would mean that each company has appropriate cash on the balance sheet and an appropriate debt structure consistent with the asset base that each company would have. We'll give you more information on the specifics of the capital structure as we get closer to the planned spin-off date.

DANIEL J. SPECIALE: Yes, and to that -- and Gary, thanks for the question. I mean, I think from an operating margin perspective, I think, it's a little bit premature probably to disclose that information. At this point, there's still a lot of work to be done to kind of recast that information. And we'll look to give that information as quickly as we can to you guys.

OPERATOR: Our next question is from Dewey Steadman with Canaccord.

DEWEY STEADMAN, SENIOR SPECIALTY PHARMA ANALYST, CANACCORD GENUITY LIMITED, RESEARCH DIVISION: I guess, Matt, can you frame the time line and expected cash impact from opioid litigation? And just sort of remind us of the various pushes and pulls there and then the ongoing dynamics of that.

MATTHEW K. HARBAUGH: Sure, you bet. So I think the cash impact from any sort of opioid settlement is probably a number of years away. We likely will see more activity in the back half of 2019 as it relates to the legal situation. But this thing is going to play out over a relatively long period of time. And we feel pretty good about our defense, if you will.

OPERATOR: Our next question is from David Maris with Wells Fargo.

DAVID WILLIAM MARIS, SENIOR ANALYST, WELLS FARGO SECURITIES, LLC, RESEARCH DIVISION: So just 2 questions. So first, a follow-up to that. Did you say -- I don't know if I heard it correctly that, that opioid litigation liability would go with the new co or is that staying with the old co? And then, if I can ask -- since that's really a follow-up, it's not a new question, if I can ask a separate question on a different topic, Mark, since this is the first opportunity we've had to talk in a public forum about the -- about anything, the HHS OIG advisory letter, maybe if you could just comment on how investors or how you're thinking about that impact on Acthar going forward.

MARK CHRISTOPHER TRUDEAU: Yes, happy to take both of those, David. First of all, with regards to risks and liabilities, our intention is to have the associated risks and liabilities that are appropriate for each asset base to follow those assets. So in other words, anything associated with the assets that are going to the Specialty Generics spin company, those risks and abilities would follow those assets, which would include anything around opioids or anything else in that

portfolio. Likewise, any of the risks and opportunities and liabilities associated with the brands business would follow the brands business forward.

On the second topic, around the OIG letter, I do think it's interesting how the market has responded to that or proceed to respond to it. This was simply a very straightforward opportunity that we saw to provide product to customers specifically for patients that have infantile spasms. This is a condition, as you know, it's an orphan condition, where time can be very important. And because of the fact that Acthar is, in virtually every case, a prior authorized product, sometimes it takes time for patients to have their reimbursement processed, and we wanted to ensure that patients had immediate access to the product, and that was our intention. We believe that the OIG response, while surprising, and we're disappointed by that, really has no impact on our business that we can see at this point. We saw it merely as an opportunity to provide a service to patients and to ensure that any patient that was diagnosed with infantile spasms could get immediate access to the drug when time in that particular situation is of the essence. So that's fundamentally the way we looked at it. We will continue to dialogue and work with agencies, both in the public sector and with private payers, to continue to look for opportunities to ensure access to Acthar going forward. Again, we continue to believe that Acthar is the drug that provides tremendous benefits for the appropriate patient types, particularly those patients that are highly refractory, who have tried and failed or been less successful on traditional therapies. Our investment in clinical trials are designed to demonstrate that utility. And we're very pleased with the trajectory that we see with Acthar going forward. And as we said in our last earnings call, we continue to believe that Acthar will be in excess of $1 billion in revenue in 2018, and we would see that in 2019 as well.

OPERATOR: The next question is from Elliot Wilbur with Raymond James.

ELLIOT HENRY WILBUR, SENIOR RESEARCH ANALYST, RAYMOND JAMES & ASSOCIATES, INC., RESEARCH DIVISION: Congratulations to Matt on the opportunity to lead the new public entity. Look forward to tracking your progress in that endeavor. Specifically, with respect to the generics business, how do we think about the segment numbers that have been reported over the last couple of quarters in terms of sort of representing a baseline or norm for the business going forward and thinking specifically about things like selling and marketing, which has increased quite a bit over the last couple of quarters? R&D spend has gone down quite a bit. Recognizing these are relatively small numbers but maybe a little bit difficult to sort of understand kind of what's really sort of driving that. As a follow-up to that, help us think about the potential impact of any transition services agreement. Understand it's relatively early, but trying to get a sense of how we should think about allocating currently unallocated G&A to the Specialty Generics business.

MATTHEW K. HARBAUGH: Thank you, Elliot. You were a bit faint, so I'm hoping I'll be able to answer all the questions that were in there. And I appreciate the comments. I'm very excited, as you might imagine, to take the company out if, in fact, that does occur in 2019. The margins that you see in the disposal group, I think it's important just to highlight that AMITIZA is going to go into the Specialty Generics business at the point of spin. And so you'll need to, as you're adjusting your model, put that into your thinking. Obviously, the numbers around that business, we do disclose the revenue. And you can see the margin profile if you go back to historical frame Sucampo Financials as it relates to gross profit and such. As it relates to the Specialty Generics business, I would say, this year, particularly the first and third quarter from a net sales perspective, had significant pressure. And we see that lessening likely as we get into 2019, still going to be under pressure. Pricing is tough out there in the market. Our methylphenidate ER product also has a fair bit of risk around it. But we are likely to see the net sales decline start to slow from what we've seen historically. From a gross profit perspective, it's in a reasonable range. It always has some pressure around it, but the significant pressure we've seen over the last couple of years is starting to dissipate as the revenue starts to strengthen a little bit more from what we've seen. And then as it relates to below the line, I'd say the R&D spend level that we're at right now is a reasonable range as we move into 2019. We're very focused on the productivity. We're hopeful to hear back from the agency on the AdCom as it relates to Roxicodone ADT, for instance, so we do have investment there. If we are able to achieve an approval for that product, we will have some incremental investment that we'll make moving into 2019

because we do believe the formulation that we have would apply to other IR formulations. And obviously, if we do get approval, that would be a welcome change for the marketplace. And then, finally, you were asking about our selling and marketing. I would say generally that's relatively flat, about 1/3 of that spend is freight. So it's directly associated with the net sales that we book. But generally, the SG&A has always been lean and mean.

OPERATOR: Our next question is from Irina Koffler with Mizuho.

IRINA RIVKIND KOFFLER, MD OF AMERICAS RESEARCH & SENIOR ANALYST, MIZUHO SECURITIES USA LLC, RESEARCH DIVISION: Will there be any potential change to the capital allocation strategy with the new CFO on the specialty business? And also can you comment on the AMITIZA OTC rates? Will they be accompanying AMITIZA into the generics piece of the business?

MARK CHRISTOPHER TRUDEAU: Yes, thanks, Irina. So with regards to capital allocation strategy and prioritization, again, that is currently unchanged from what we've been saying throughout 2018, meaning that our primary use of capital, at least through 2018, will continue to be focused on repayment of debt. Our 2019 capital allocation strategy will be discussed at a later point. But again, I just want to remind folks on the call that, essentially, what we've done is to prioritize debt repayment in the near term to continue to delever our balance sheet. But it doesn't preclude us from using capital in other ways, which would include share repurchases and M&A, and you should expect us to do that from time to time as well. But at this point, our capital allocation prioritization is unchanged for the brands business. With regards to AMITIZA OTC rates, that would also go with the entire AMITIZA portfolio to the spin company.

OPERATOR: Our next question is from David Amsellem with Piper Jaffray.

MICHAEL ELLIOT INGERMAN, RESEARCH ANALYST, PIPER JAFFRAY COMPANIES, RESEARCH DIVISION: This is Mickey Ingerman on for David. First, how does the company think about AMITIZA cash flows once the first generic from Endo enters, given that it is a somewhat challenging product? I guess, put another way, could it still be a meaningful source of cash flow even after generics emerge? And then just briefly how are you guys thinking about R&D for the new co?

MARK CHRISTOPHER TRUDEAU: And so maybe I can take a little bit of the first question and ask Matt to comment, certainly, on it as well and also the second question. So again, just remember the way the AMITIZA deal is structured, even after the introduction of the first generic, there's a value share agreement between the parties which would ensure an ongoing significant income stream from that product that would continue to accrue for an additional 1 to 2 years. So our belief is that the cash flow generation for AMITIZA will continue to be quite healthy over the next several years.

MATTHEW K. HARBAUGH: As it relates to the R&D question for new co, I think the spend level as we move into 2019 will stay roughly in the same range that we see for 2018. One of the elements of our pipeline is a number of our larger products, our complex generics that we plan to launch, are kind of in the latter years, in the 2022, 2023 timeframe. And so the goal would be, with the challenges that will come to AMITIZA during that timeframe, that our pipeline will kick in at that point and give us new revenue streams.

OPERATOR: Our next question is from Louise Chen with Cantor Fitzgerald.

SUDAN NAVEEN LOGANATHAN, ANALYST, CANTOR FITZGERALD & CO., RESEARCH DIVISION: This is Sudan in for Louise. So our first one is on why not -- sorry, when do you expect the decline in generics to kind of turn around? And how should we think about the sales growth, the decline of the spin-out business over the next several years? And then why not keep the business and collect the cash for pay down debt, increase dividend, et cetera?

MATTHEW K. HARBAUGH: Yes, this is Matt. I would say, as I mentioned earlier, the decline we saw this year is greater than what we foresee as we move into 2019. Very hard to predict when the price harmonization in the marketplace fully does come to a full stop. I'd say the other element that's been going on in our business over the last couple of years that I would focus on is on modeling this out is the methylphenidate ER product has been declining over the years. And what we found is that the BX-rated product which ourselves and Lannett sell, as more competitive entrants are coming into the marketplace, the pricing has gotten pressured across the board. And so the methylphenidate ER product will also continue to decline in the next year. But in future years, you will see less of an impact on that.

MARK CHRISTOPHER TRUDEAU: And maybe with regards to the second question, I just would refer you back to the way we've described what we're looking to do with Specialty Generics business. Our fundamental objective is to create shareholder value and we believe that this is the best way to create shareholder value and move the Specialty Generics business and separate it from the Specialty Brands business. If we go back to the prepared comments, we've been talking about this in the market for quite some time that we were pursuing a range of strategic options to separate the generics business. We put it in the discontinued operations earlier this year to signal that intent. And we've been working diligently across a range of strategic options to look for the best way to maximize shareholder value. We believe that the announcement today is a representation of that and that the separation of these 2 businesses makes very good strategic and economic sense because it really enables the 2 businesses, which not only operates separately but have dramatically different business models, customer bases, portfolios and strategic intent to maximize value for shareholders by pursuing those independent strategies with companies that are at scale and appropriately capitalized and can enable each of those management teams to focus on driving those things that create value for those very independent businesses.

OPERATOR: Our next question is from Patrick Trucchio with Berenberg Capital Markets.

PATRICK RALPH TRUCCHIO, ANALYST, JOH. BERENBERG, GOSSLER & CO. KG, RESEARCH DIVISION: I just have a follow-up on your view of the generics and AMITIZA business prospects. So I hear your optimism for these businesses, but what specifically can you point to that will make the revenue pressure ease in 2019 and beyond? And if it's new products, can you tell us which ones or can you tell us how many ANDA filings are outstanding? And if it's also from less pressure on opioids, can you tell us why that would happen?

MATTHEW K. HARBAUGH: Yes, so a couple of things I would say to that. The first thing is, we, in our prepared remarks, talked about how we'll provide more information in the Form 10. So it's a bit too early to be digging into the pipeline. This being said, I would go back to what I said on the last question which is the lion's share of the revenue stream that we see coming out of our pipeline is kind of 4, 5 years out. And so AMITIZA will help us as we transition to the portfolio. Notably though, I'd say, greater than 50% of the products in our ANDA portfolio are what we call complex generics. They are not controlled substances. With regard to the controlled substance market, what we are seeing is a couple of things. One, over the last few years, we actually have been taking more share in the dosage business. And we anticipate that, that may continue as we move into future years. The market itself will still decline but we also see, right now, in the marketplace, continuity of supply is very important to our customers. And so some of the aggressive pricing harmonization that we've seen historically has somewhat moderated as perhaps some manufacturers have left the market.

OPERATOR: Our next question is from Annabel Samimy with Stifel.

ANNABEL EVA SAMIMY, MD, STIFEL, NICOLAUS & COMPANY, INCORPORATED, RESEARCH DIVISION: I want to ask you about the remaining company, the Specialty Brands business. Given that you had separated generics into discontinued, what kind of margins can we expect for the remaining Specialty Brands business? Is it fair to say that the margins that are right now in the business are what's going to remain for that Specialty Brands business? And can you maybe talk about cash flow impact given that the key benefit for the Specialty Generics from an -- I guess an accounting perspective was really continued cash flow for the brands?

MARK CHRISTOPHER TRUDEAU: Yes. Thanks, Annabel. I'm happy to take both of those and Dan may have some comments as well. So with regards to the margin question, I think Dan mentioned earlier, we'll give more specifics obviously, when we get closer to spin. But one thing that I can say in general is that if you look at how the business has transformed over the last several years, there's been a dramatic increase in both gross profit as a percent of sales, EBITDA margin -- virtually all elements of profitability margins have continued to increase and are now approaching those that would be consistent with what you would typically see in a typical specialty pharmaceutical business that's focused on drug development and commercialization. And we would expect those trends to continue and that type of margin structure to continue to be the case toward the brands business. With regards to cash flow, again, I go back to the description of how we plan to capitalize both of these businesses. We've talked about appropriate capitalization, and that means cash on the balance sheet and a debt structure that is consistent with the assets that each company would maintain. And an important consideration here is that we do anticipate that this is likely to be a levered spin. And as such, it should provide additional liquidity to the brands business to help us continue to invest in the business and to pursue our capital allocation strategy which it would include debt paydown, share repurchases and M&A but focused and consistent with the strategic objectives of that brand business, which would be to enhance the portfolio, both developmentally and commercially with products that are focused on underserved patients in severe and critical conditions.

OPERATOR: Our next question is from Ami Fadia with Leerink.

AMI FADIA, DIRECTOR OF BIOPHARMA & GENERICS AND SENIOR ANALYST, LEERINK PARTNERS LLC, RESEARCH DIVISION: I've got 3 quick questions. Firstly, Matt, congratulations on the new role. Can you give us a little bit more details on how many products you have in the generics pipeline and a little bit of color on kind of how far out they are in the development process? Secondly, what type of leverage levels are you guys anticipating for both the entities after the spin out? And thirdly, just as we try to understand the operating expenses of the 2 separated companies, are there additional expenses that maybe the generics company may need to undertake now that it will be a completely sort of separate entity? Can you give us a little bit color on that?

MATTHEW K. HARBAUGH: Sure. Thank you, Ami. Let me answer your Specialty Generics questions, and then I'll turn it over to Dan as it relates to the leverage. So as I mentioned earlier, we will likely give a bit more color on our pipeline as we get to filing the Form 10. It's a bit early yet to be disclosing some of that information at this point. But I would highlight my comment earlier which is we do have a pipeline. We've been investing in it over a number of years. And the evidence of that was the successful AdCom that we had a number of weeks ago on our Roxicodone abuse-deterrent technology. And as I mentioned earlier, we are hopeful that we will get an approval from FDA for that particular technology because then we would in turn take that innovative product and apply it to other IR formulations to make opioids safer across the United States. So from a pipeline perspective, though, as we think about the products, the complex generic products we have in the pipeline, the larger scale products are in the 2022, 2023 timeframe. So it's going to take some time to see some of the benefit from those investments that we've put in particularly over the last couple of years. As it relates to the Specialty Generics expenses, the only thing I would highlight is we will have some incremental costs associated with spinning the business out. Obviously, we're going to put in a fair bit of expense associated with the board and auditing and finance. But the underlying expenses in the Specialty Generics business that you see in discontinued operations are likely to stay relatively in the same range over time.

DANIEL J. SPECIALE: Yes. To your question specifically about leverage, I mean, we're obviously not at a point today to be able to speak definitively about where those will ultimately be. Much of that will be determined over time. I think the important piece today is that we do expect it to be a levered transaction, as Mark indicated. And we'll certainly have more information to share as time goes on.

OPERATOR: Our next question is from Jason Gerberry with Bank of America.

JASON MATTHEW GERBERRY, MD IN US EQUITY RESEARCH, BOFA MERRILL LYNCH, RESEARCH DIVISION: I just wanted to come back to the AMITIZA profit contribution. If I go back to the Sucampo Financials a lot of the costs that -- whatever were there weren't really affiliated or associated with AMITIZA. So am I safe to assume that this is basically 100% profit margin product for you. And if we do that and strip it out of the brand business, which is continuing operations, it has about a 300 basis point impact on branded margin. So any color or commentary you can just provide on that, kind of rough math, is it crazy, is it directionally accurate, would be much appreciated.

DANIEL J. SPECIALE: So I think the thing that you're probably missing a little bit when you look at the AMITIZA results is that we actually do manufacture that product in addition to having a royalty stream associated with it. So the cost structure is not 100%. There is certainly a royalty component to it. And yes, that piece of it is 100% margin. But the margin associated with the product sales are relatively modest.

OPERATOR: Our next question is from Dana Flanders with Goldman Sachs.

CHRISTOPHER JOHN STARAL, RESEARCH ANALYST, GOLDMAN SACHS GROUP INC., RESEARCH DIVISION: This is Chris Staral on for Dana. So just as you were considering all strategic options for the generics business, what were some of the factors that were accounting for maybe some of the disconnect that you're seeing between the valuations that you were looking for and what was on the table? And then did the decision to ultimately spin this off relate at all to timing on meeting the pull back to disposal group given the accounting rules associated with time limitations and keeping a disposal group out there on your financials?

MARK CHRISTOPHER TRUDEAU: Yes, happy to take those. So again, when we put the business in discontinued operations, it was a clear signal that we were planning to separate this business in the near term. And again, I go back to the prepared comments when going back to 2016, we had had numerous discussions at the board level about what were the range of options that we should consider to separate this business because, again, strategically where the brands business was heading and where the generics business were heading were clearly in 2 different directions. So putting the business in discontinued operations was a significant step forward in describing to the market that we were planning in the near term to separate these 2 businesses. And again, we've consistently said that we would pursue all options, which would include sale in whole or in parts, arrange a partnership opportunities, joint ventures, variety of spin-off alternatives. And we have continued to progress those alternatives and will continue to progress those alternatives certainly until the spin executes, again, towards the second half of 2019 or sooner. Again, our primary objective here is simply to maximize shareholder value and to enable each of the businesses to pursue their own individual strategies which are pretty separate and different. We believe that's the best way to maximize shareholder value. If additional opportunities emerge over the next several months that would enhance or increase shareholder value beyond this particular option, we would certainly consider those as well.

MATTHEW K. HARBAUGH: And I would just add that in our prepared remarks, we talked about, and it's actually in the release from this morning, we've been looking at these alternatives since 2016. So this is a long time horizon that we've been exploring options.

OPERATOR: Our next question is from [Nuvan Thai] with Citi.

UNIDENTIFIED ANALYST: So I understand that it's early stage, but could you please comment on the bonds and debt. So could some existing debt be transferred to the new entity? Or will the spin-off entity raise new debt? And do you expect more debt at the Specialty Generics unit? Some initial thoughts will be helpful.

DANIEL J. SPECIALE: [Nuvan], thanks very much for the question. I mean, I certainly appreciate where you're coming from. I think at this point, we really don't have a tremendous amount that we can share on what the desired path is other

than that they will have debt. What mechanism by which we will either provide them debt or raise debt for them has not been stated at this point, so.

MARK CHRISTOPHER TRUDEAU: Yes, and just one additional comment on that because I know there's been several questions. Again, we do anticipate that this is likely to be a levered spin. We do anticipate that, that will create liquidity for the brands business. We also believe that cash flow for both companies will continue to be robust. And if you look at Mallinckrodt as a whole, cash flow generation has been a hallmark of the company. And we would anticipate that, that would continue to be the case for both the spin co and the remaining brands business.

OPERATOR: Our next question is from John Boris.

JOHN THOMAS BORIS, MD, SUNTRUST ROBINSON HUMPHREY, INC., RESEARCH DIVISION: Congrats, Matt, on running the spin co here. Just -- first question, just on the timing of the Form 10, when would you expect that to be issued? Second question, can you just give us a little bit of sense on what volumes and how much price is down in 2018 for that segment? Also, can you just give some commentary, especially since the FDA has initiated a REMS program for opioid analgesic use and what the implications of that are going forward? And then the last question just has to do with how you're thinking about domiciling the company, where will it be domiciled?

MATTHEW K. HARBAUGH: Yes. So thank you, John. I appreciate your comments. I'll start with your last question. The domicile of the spin co will be the United States, and the headquarters of the Specialty Generics business will be in St. Louis. We are well aware of the REMS program from an FDA perspective. And we do invest money there, and that's part of what we do. It's part of being in the controlled substance market. So I don't think you should think that it has any sort of outsized implications from a financial perspective. It's kind of our bread and butter in what we do. As it relates to the timing of the Form 10, we expect to do that in the early part of 2019. As you might imagine, there's a lot of work that needs to be done as Dan highlighted earlier. So we'll give more color on that as we move into next year. But rest assured, we're already launching into action. And there's priority here obviously because we did many a Form 10 back in the day when we were spun just a mere 5 years ago. And largely the same team that worked on that is working on it now. So we are very familiar with the process involved here. And then finally, as it relates to volumes and price, generally, what I would say is price has been where the pressure has been this past year and in previous years. And what we're hoping is that the price harmonization that's occurred becomes less severe as we move into future years and that it really rests on volumes as we move forward. I would say generally, though, the pricing flexibility is still under pressure as we move into '19.

DANIEL J. SPECIALE: Thank you very much, John, for the question, yes. And unfortunately, I think we're coming up on the top of our time here. So I want to thank everyone for joining us again this morning on such short notice. As a reminder, a replay of the call will be available on our website later today. And again, I'll also be available throughout the day to answer any follow-up questions any of you may have. So thanks everyone, and have a great day.

OPERATOR: Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program, and you may all disconnect. Everyone, have a great day.

looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

---- Index References ----

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News Subject: (Business Management (1BU42); Chief Financial Officer (CFO) Changes (1CH08); Corporate Events (1CR05); Corporate President Changes (1CH06); Earnings Calls (1EA37); Executive Personnel Changes (1EX23); HR & Labor Management (1HR87); Meeting Announcements (1ME17))

Industry: (Drug Approval Process (1DR91); Drug Discovery & Development Process (1DR41); Generic Drugs (1GE93); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Research & Development (1PH57))

Region: (Americas (1AM92); Asia (1AS61); Eastern Asia (1EA61); Far East (1FA27); Japan (1JA96); North America (1NO39))

Language: EN

Other Indexing: (AMITIZA; ASC LLC; BMO Capital Markets; CANTOR FITZGERALD & CO.; Specialty Generics; WELLS FARGO SECURITIES LLC) (Gary Nachman; John Boris; JASON MATTHEW GERBERRY; DAVID WILLIAM MARIS; ELLIOT HENRY WILBUR; Mark C. Trudeau; Mark Trudeau; DANIEL SPECIALE; MICHAEL ELLIOT INGERMAN; Patrick Trucchio; Mickey Ingerman; Matthew K. Harbaugh; Matthew Harbaugh;

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